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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,711	01/22/2002	Edward Rebar	8325-0025	6236

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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/055,711	Applicant(s) REBAR ET AL.	
	Examiner Terry A. McKelvey	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/23/05 and 9/1/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 30-53 is/are pending in the application.
- 4a) Of the above claim(s) 1,3,5,7-9,11-21,23,24,33-35,38 and 42-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4,6,10,22,25-28,30-32,36,37,39-41 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/11/05 and 9/1/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Claims 1, 3, 5, 7-9, 11-21, 23-24, 33-35, 38, and 42-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/3/04 and 11/18/04.

In the reply filed 5/23/05 applicants note that although claims 3, 5, 7-9, 11-21, 23, 24, 33-35, and 38 have not yet been considered, they are not withdrawn as the result of a restriction requirement, rather they are non-elected species that will be considered upon allowance of a generic claim. In response, claims to non-elected species are withdrawn; that is their proper status. If they are considered as a result of the allowance of a generic claim, their status will change, as will the status of any non-elected claim that is subject to rejoinder.

The applicant also indicates that claim 30 is a linking claim linking the proteins of Group I which are encoded by the polynucleotides of Group II with the methods of Group III. This is not correct because claim 30 is drawn to an isolated

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polynucleotide, Group I is drawn to an isolated protein, and Group III is drawn to a method of using the polynucleotide of Group II and does not use the protein of Group I as claimed.

The applicant is correct that the restriction requirement has been made final in the prior Office Action (although this was not explicitly stated).

This application contains claims 1, 3, 5, 7-9, 11-21, 23-24, 33-35, 38, and 42-52 drawn to an invention nonelected with traverse in the papers filed 8/3/04 and 11/18/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4, 6, 10, 22, 25-28, 30-32, 36-37, 39-41, and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the

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specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new rejection necessitated by the applicant's amendment to the claims filed 5/23/05.

The claims are drawn to an isolated polynucleotide encoding a non-naturally-occurring zinc-finger binding protein comprising a non-canonical zinc finger component, wherein said non-canonical zinc finger component contains a beta turn comprising the two amino-terminal zinc coordinating residues and an alpha helix comprising the two carboxy-terminal zinc coordinating residues, and the zinc-coordinating residues do not consist of two cysteine residues and two histidine residues and wherein the protein is engineered to bind to a target sequence. Thus, the claims are drawn to a genus of compounds that is defined by a non-canonical zinc finger structure which has the general structure of a canonical zinc finger (with regard to the structure of the beta turn and alpha helix), but has a different set of amino acids as the zinc coordinating amino acids.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of

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complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

In the instant case, while the claims contain a description of a general structure drawn to the non-canonical zinc finger component containing a beta turn comprising the two amino-terminal zinc coordinating residues and an alpha helix comprising the two carboxy-terminal zinc coordinating residues, the structure is further limited by excluding the C2H2 structure which supports that structure, instead claiming a retention of the structure without use of the standard C2H2 zinc coordinating residues. In other words, what is claimed is a structure where the critical C2H2 residues which are used to support the structure have been replaced with amino acid residues that are not C2H2 (and whatever other amino acid changes are needed to support that replacement of the zinc coordinating residue(s)). The claims and specification further limit the non-canonical zinc finger to different sequences (e.g., claim 6), but a review of these sequences shows that the sequences merely are very broad sequences which correspond to canonical sequences in which one of the zinc coordinating residues has been replaced with some other non-specified amino acid. These sequences provide no

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further structure as to which particular amino acid sequences can replace the C2H2 zinc coordinating residues while maintaining the canonical general structure. A review of the specification identified multiple examples of only one general type of non-canonical zinc finger protein meeting the claim limitations: a zinc finger protein in which the zinc coordinating residues are C2HC. There does not appear to be a description of any other zinc fingers which meet the claim limitations which have a different set of zinc coordinating residues and the detailed chemical structure of such structures are unpredictable in the art in the absence of empirical determination. Accordingly, in the absence of sufficient recitation of distinguishing characteristics (e.g., specific sequences) drawn to other types of non-canonical zinc fingers which retain the canonical structure using zinc coordinating residues that are neither C2H2 nor C2HC (the only structures whose sequences are specifically described), the specification does not provide adequate written description of the claimed genus which encompasses all non-canonical zinc fingers having the canonical general structure.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

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possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*."

(See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of non-canonical zinc fingers as claimed, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polynucleotides encoding a non-canonical zinc finger, wherein the zinc coordinating residues

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are drawn to the C2HC structure (and having the other claim limitations) but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent

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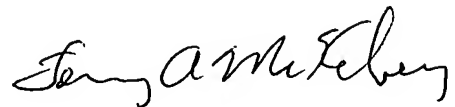
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

A handwritten signature in cursive script, reading "Terry A. McKelvey".

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

November 13, 2005